# K050034

## JAN 1 3 2005 510(K) SUMMARY

## Antares Diagnostic Ultrasound System with 4D Basic Imaging

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

#### 1. Submitted By:

Siemens Medical Solutions USA, Inc. 22010 S.E. 51st Street Issaguah, WA 98027-7298

#### **Contact Person:**

Patrick Lynch Regulatory Affairs

Phone: (425) 557-1825 FAX: (425) 391-9198

#### **Date Prepared:**

December 22, 2004

#### 2. Proprietary Name:

SONOLINE Antares™ Ultrasound System

#### **Common/Usual Name:**

Diagnostic Ultrasound System with Accessories

#### Classification Name:

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560 Product Code 90-IYO Diagnostic Ultrasound Transducer FR # 892.1570 Product Code 90-ITX

#### 3. Predicate Device:

The Antares system is multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the following products which are already cleared for US distribution with the following 510(k) clearances:

- K001400, 8/1/00, cleared as the Elegra Millennium Advanced, marketed as the
- K040060, 01/28/04, cleared as SONOLINE G50/G60 S Diagnostic Ultrasound System

#### 4. Device Description:

The Antares with 4D Basic Imaging is substantially equivalent to the predicates listed herein. The Antares is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PWD) Doppler Mode, Continuous (CWD) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, 3D imaging, and 4D Basic Imaging on a CRT display.

The Antares has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

#### 5. Intended Uses:

The Antares ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

#### 6. Technological Comparison to Predicate Device:

Antares Avant is substantially equivalent to the SONOLINE Elegra Millennium Enhanced, cleared via K001400, and the SONOLINE G50/G60 S Diagnostic Ultrasound System, cleared via K040060. All systems transmit ultrasonic energy into patients, then perform postprocessing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

December 22, 2004 Page 3



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

#### JAN 1 3 2005

Siemens Medical Solutions USA, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25<sup>th</sup> Street NW BUFFALO MN 55313

Re: K050034

Trade Name: SONOLINE Antares™ Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: January 5, 2005 Received: January 7, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE Antares<sup>TM</sup> Diagnostic Ultrasound System, as described in your premarket notification:

#### Transducer Model Number

CW2 CW5 C5-2 Curved Array CX5-2 Curved Array VF7-3 Linear Array
EC9-4 Curved Array
VFX9-4 Linear Array
VF10-5 Linear Array
VF13-5 Linear Array
VFX13-5 Multi-D Array
PX4-1 Phased Array
MPT7-4 Multiplane TEE

CH6-2 Curved Array
PH4-1 Phased Array
P10-4 Phased Array
VF13-5SP Linear Array
C5F1 Curved Array
C7F2 Curved Array
EV9F4 Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Vancy C. Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

#### **FDA Cleared Indications for Use Forms**

510 (k) Number (if known):

Device Name:

**SONOLINE Antares** 

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Μ	ode of Oper	ation	<u></u>	
Clinical Application	А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Abdominat		₽	Р	Р	Р	P	Р	<del></del>	BMDC	Note 2,3,4,5,7,8
Intraoperative (Note 9)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological		Р	Р	Р		Р	Р	•	BMDC	Note 2,3,4,5,7,8
Pediatric		Ρ	Ρ	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		Ρ	Р	ρ	Р	Р	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8
Cardiac		Р	Р	Р	Р	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,6
Transrectal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Transvaginal		Р	P	P		P	Р		BMDC	Note 2,3,4,5,7,8
Transurethral										- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
Intravascular										
Peripheral vessel		Р	P	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### **Additional Comments:**

12/22/2004

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sigl-Off)

Division of Reproductive, Abdomin

and Radiotogical Devices

510(k) Number

2050034

510 (k) Number (if known):

Device Name: Intended Use:

CW2 Probe for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

						М	ode of Opera	ation		<u> </u>
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р					
Abdominal					P					· · · · · · · · · · · · · · · · · · ·
Intraoperative (Note 9)					Р					,
Intraoperative Neurological										
Pediatric					Р					
Small Organ (Note 1)					Р					•
Neonatal Cephalic					Р					
Adult Cephalic					P					
Cardiac					Р					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral								4		
Intravascular										
Peripheral vessel					Р					
Laparoscopic									<u> </u>	
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (specify)								17.b.		

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number <u>4050034</u>

510 (k) Number (if known):

Device Name: Intended Use: CW5 Probe for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

a <sup>2</sup>						М	ode of Oper	ation	<u></u>	
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic						· · · · · · · · · · · · · · · · · · ·				
Fetal					N					· · · · · · · · · · · · · · · · · · ·
Abdominal					N					<del></del>
Intraoperative (Note 9)					N					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Intraoperative Neurological				٠.						
Pediatric					N			-		***
Small Organ (Note 1)					Ŋ					
Neonatal Cephalic					N	•		·		
Adult Cephalic					N		İ			
Cardiac					N					
Trans-esophageal										
Transrectal				·						<del></del>
Transvaginal										
Transurethral										**
Intravascular										·
Peripheral vessel					N					
Laparoscopic						-				<del></del>
Musculo-skeletal Conventional					N					<u> </u>
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number\_

510 (k) Number (if known):

Device Name: Intended Use:

C5-2 Curved Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

	<u> </u>	Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic ,										· · · · · · · · · · · · · · · · · · ·		
Fetal		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8		
Abdominal		Р	Р	Р		Ρ	Р	<u>.</u>	BMDC	Note 2,3,4,5,7,8		
Intraoperative Abdominal						<u> </u>				· <del></del>		
Intraoperative Neurological	ļ					·						
Pediatric		P	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8		
Small Organ		L			<u> </u>							
Neonatal Cephalic	Ĺ						ļ					
Adult Cephalic		Ĺ								···		
Cardiac												
Trans-esophageal					<u> </u>					·		
Transrectal							<u> </u>		<b> </b>			
Transvaginal									L			
Transurethral			<u> </u>							···· <u>······</u>		
Intravascular	[											
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8		
Laparoscopic			<u> </u>		<u> </u>		ļi					
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8		
Musculo-skeletal Superficial												
Other (specify)	T											

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### **Additional Comments:**

Note 2	Ensemble	tissue	harmonic	imaging
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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_\_\_\_\_

510 (k) Number (if known):

Device Name: Intended Use:

CX5-2 Curved Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

			··			Мс	ode of Opera	ation		
Clinical Application	Α	∵В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8
Abdominal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		·Ρ	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic			<u> </u>						1	
Adult Cephalic			<u> </u>							
Cardiac									L	
Trans-esophageal									<u> </u>	
Transrectal		<u> </u>							•	
Transvaginal										
Transurethral			<u> </u>							
Intravascular		·	<u> </u>						<u> </u>	
Peripheral vessel		Ρ	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic									ļ. <u>.</u> .	
Musculo-skeletal Conventional		Р	P	Р		Р	Р		вмрс	Note 2,3,4,5, <b>7,</b> 8
Musculo-skeletal Superficial										
Other (specify)			<u> </u>		<u> </u>					

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### **Additional Comments:**

Ensemble tissue harmonic imaging Note 2 SieClear multi-view spatial compounding Note 3

Tissue Equalization Technology Note 4

3-Scape real-time 3D imaging Note 5

B&W SieScape panoramic imaging Note 7

Power SieScape panoramic imaging Note 8

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510 (k) Number (if known):

Device Name: Intended Use:

VF7-3 Linear Array Transducer for use with SONOLINE Antares
'Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	P		Ρ	₽		BMDC	Note 2,3,4,5,7,8		
Abdominal		Р	Р	Р		Ρ	P		BMDC	Note 2,3,4,5,7,8		
Intraoperative Abdominal												
Intraoperative Neurological												
Pediatric		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8		
Small Organ (Note 1)		Ε	Ε	E		E	E		BMDC	Note 2,3,4,5,7,8		
Neonatal Cephalic									I			
Adult Cephalic												
Cardiac							<u> </u>		<u> </u>			
Trans-esophageal										<u> </u>		
Transrectal				<u> </u>					l			
Transvaginal												
Transurethral						·			<u> </u>	·		
Intravascular										·		
Peripheral vessel		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8		
Laparoscopic												
Musculo-skeletal Conventional		Р	P	Р		P	Р		вмос	Note 2,3,4,5,7,8		
Musculo-skeletal Superficial		Е	E	Е		ш	E		BMDC	Note 2,3,4,5,7,8		
Other (specify)												

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 1	For example	e: breast,	testes,	thyroid,	penis,	prostat	e, etc.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)/

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number <u>60500.39</u>

12/22/2004

510 (k) Number (if known):

Device Name: Intended Use: EC9-4 Curved Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

<del>,</del>	Γ				<u></u>	Me	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	ســـــــــــــــــــــــــــــــــــــ									N-1 00 1 5 7 0
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal	Ι		<u> </u>			<u> </u>		····		
Intraoperative Abdominal					ļ <u>.</u> .					
Intraoperative Neurological	<u> </u>				ļ					<u> </u>
Pediatric		<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>	<del>   </del>	
Small Organ (Note 1)		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E	ļ	E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic	<u> </u>	<u> </u>		<u>  </u>		<u> </u>	ļ		<del> </del>	
Cardiac		<u> </u>	<u> </u>	ļ	ļ		<b> </b>		<del>   </del>	
Trans-esophageal	ļ	<u> </u>		ļ <u>.</u>	<b> </b>		P -		BMDC	Note 2,3,4,5,7,8
Transrectal	<u> </u>	Р	Р	P	<b>├</b>	P	P		BMDC	Note 2,3,4,5,7,8
Transvaginal	1	P	P_	<u> </u>	<del> </del>	P	<del>                                     </del>	<u> </u>	- DIVIDO	14016 2,0,4,0,7,0
Transurethral	<del> </del> _	↓	ļ	<del> </del>	<del></del>	<del> </del>	<del> </del>	<u> </u>	<del> </del>	<del></del>
Intravascular	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<del></del>	<u> </u>	<del>                                     </del>	····
Peripheral vessel	<u> </u>	<u> </u>	ļ	<del> </del>	<b>↓</b> —		<del> </del> -	ļ	<del> </del>	·
Laparoscopic	ļ	1_	<del> </del>	<del> </del>	<u> </u>	ļ	<del> </del>	<del></del>	<del> </del>	
Musculo-skeletal Conventional							ļ		<u> </u>	
Musculo-skeletal Superficial										
Other (specify)		<u> </u>	<u> </u>			<u> </u>	nddad yade	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 1	For example: breast,	testes, thyroid,	penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number <u>1,050034</u>

510 (k) Number (if known):

Device Name: Intended Use:

VFX9-4 Linear Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

			:			М	ode of Opera	ation		
Clinical Application	Α	B	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	P		P	Р		BMDC	Note 2,3,4,5,7,8
Abdominal		Ρ	Ρ	Ρ		P	Р		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Ρ	Р		P	Р		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		Ð	Р	Đ.		ρ	P		вмос	Note 2,3,4,5,7,8
Neonatal Cephalic		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac					_					
Trans-esophageal										
Transrectal									<u> </u>	
Transvaginal										
Transurethral						·				
Intravascular									1	
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		E	E	E		E	Е		BMDC	Note 2,3,4,5,7,8
Other (specify)					24.1600			A		

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 1	For example:	breast, testes,	thyroid,	penis,	prostate, e	etc.
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Note 2 Ensemble tissue harmonic imaging

SieClear multi-view spatial compounding Note 3

Note 4 Tissue Equalization Technology

3-Scape real-time 3D imaging Note 5

B&W SieScape panoramic imaging Note 7

Note 8 Power SieScape panoramic imaging

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)/ Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

510 (k) Number (if known):

Device Name: Intended Use:

VF10-5 Linear Array Transducer for use with SONOLINE Antares
Ultrasound imaging or fluid flow analysis of the human body as follows:

	<u></u>			·		М	ode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			T					<u></u>		
Fetal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8
Abdominal		P	Р	P.		P	Р	···	BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										11010 2,0,4,0,7,0
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		₽	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		Ď.	Ρ	Р		Ρ	Р		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										110.0 2,0,7,0,7,0
Cardiac										· · · · · · · · · · · · · · · · · · ·
Trans-esophageal										<del></del>
Transrectal			-			~~	•			<del></del>
Transvaginal					1					
Transurethral	一				1			<del></del>	<del></del>	
Intravascular										<del></del>
Peripheral vessel		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										11010 2,0,4,0,7,0
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8
Other (specify)						-	<del>  </del>	·	<del></del>	· · · · · · · · · · · · · · · · · · ·

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number K05003L

510 (k) Number (if known):

Device Name: Intended Use:

VF13-5 Linear Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic								<u> </u>		····
Fetal		E	E	E	, ·	Ε	E		BMDC	Note 2,3,4,5,7,8
Abdominal		E	Ε	E		E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										<del>.</del>
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		Ð	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		Е	Ε	E		E	E	·	BMDC	Note 2,3,4,5,7,8
Adult Cephalic										***************************************
Cardiac										
Trans-esophageal										· · · · · · · · · · · · · · · · · · ·
Transrectal										
Transvaginal										
Transurethral										
Intravascular			- }							- <del></del>
Peripheral vessel		Ρ	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		Р	Р	Р		Ρ	Р	T	BMDC	Note 2,3,4,5,7,8
Other (specify)	$\neg \uparrow$	$\neg$								·

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note	1	For examp	ile: breast,	testes, th	yroid, p	enis,	prostate, etc	>.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number <u>KN50034</u>

510 (k) Number (if known):

**Device Name:** Intended Use: VFX13-5 Multi-D Array Transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

			,			M	ode of Opera	ation	<del></del>	
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	Ε	Ε		E	E	<del></del>	BMDC	Not contain
Abdominal		E	E	Ε		E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal									BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological		i								
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2.2 4.5.7.0
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8 Note 2,3,4,5,7,8
Neonatal Cephalic		Ε	Е	E		Ε	E		BMDC	
Adult Cephalic	$\neg \neg$			t				<del></del>	BIVIDC	Note 2,3,4,5,7,8
Cardiac		一					<del></del>	<del></del>	<del></del> -	
Trans-esophageal										<del></del> -
Transrectal			$\neg \neg$			<del></del>	<del></del>			
Transvaginal	$\neg \neg$									<del>-</del>
Transurethral		_		<del></del>	<del></del>					
Intravascular		$\neg \uparrow$								
Peripheral vessel	$\neg \uparrow$	P	P	P	<del> -</del>	P	P	<del></del>	2140.0	<u> </u>
Laparoscopic			<del>-  </del>	<del>- +</del>	<del></del> }-	<del>-                                    </del>			BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Conventional		P	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Other (specify)						—— <u> </u>	<del></del>	<del></del>		11000 2,0,4,0,7,0

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 1	For example:	breast, te	estes, thyroid	nenis	nrostata	oto.
M-4-0				P	prostate,	CIŲ,

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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> > Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

510 (k) Number (if known):

Device Name: Intended Use:

PX4-1 Phased Array Transducer for use with SONOLINE Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

				,		M	ode of Oper	ation		<del></del>
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<del></del>
Fetal		Р	P	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8
Abdominal		Р	Р	Р	Р	Р	Р		BMDC	
Intraoperative Abdominal						:			DIVIDO	Note 2,3,4,5,7,8
Intraoperative Neurological									-	<del></del>
Pediatric		2	Р	Р	Р	Р	Р	·	BMDC	Note 2 2 4 5 7 0
Small Organ								_	Biolog	Note 2,3,4,5,7,8
Neonatal Cephalic		Р	ρ	Р	P	P	P		BMDC	Note 00 4 5 7 0
Adult Cephalic		Ρ	Р	Р	P	P	P		BMDC	Note 2,3,4,5,7,8
Cardiac		Р	Ρ	P	Р	Р	Р	<del></del>	BMDC	Note 2,3,4,5,7,8
Trans-esophageal							<del></del> +		BIVIDC	Note 2,3,4,5,6,7,8
Transrectal		T			<del></del> +		<del></del>			<del></del>
Transvaginal					$\neg$				<del></del>	·
Transurethral		寸			~		<del></del>			<del></del>
Intravascular			$\neg \uparrow$		<del></del>				<del></del>	
Peripheral vessel		Р	P	P	P	Р	Р		BMDC	M
Laparoscopic		$\neg \neg$		<del></del>	<del>+</del>	<del></del>	<del></del> '		PMDC	Note 2,3,4,5,7,8
Musculo-skeletal Conventional										·
Musculo-skeletal Superficial					$\neg \neg$					
Other (specify)				<del> </del> -			-	<del></del>		<del> </del>

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional	Comments:
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١	lote	2	Ensemble	tissue	harmonic	imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

3-Scape real-time 3D imaging Note 5 Note 6

Cadence contrast agent imaging

B&W SieScape panoramic imaging Note 7

Note 8 Power SieScape panoramic imaging

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> > Prescription Use (Per 21 CFR 801,109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

050034 510(k) Number\_

510 (k) Number (if known):

Device Name: Intended Use:

MPT7-4 Multiplane TEE Transducer for use with SONOLINE Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation	`	
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<del> </del>
Fetal								····		<del></del>
Abdominal								······································	<del>                                     </del>	·
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ					1					
Neonatal Cephalic										<del></del>
Adult Cephalic							_			<del> </del>
Cardiac			·	- 1					<del></del> -	
Trans-esophageal		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,6
Transrectal										11010 2,0,4,0,0
Transvaginal			ĺ							· <u> </u>
Transurethral									<del></del>	<del></del>
Intravascular			$\Box$							<del></del>
Peripheral vessel										<del> </del>
Laparoscopic					1					
Musculo-skeletal Conventional		ĺ								
Musculo-skeletal Superficial						**				
Other (specify)						···		<del></del>	<del></del>	<del></del>

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 2	Ensemble	tissue	harmonic	imaging
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SieClear multi-view spatial compounding Note 3

Note 4 Tissue Equalization Technology 3-Scape real-time 3D imaging Note 5

Note 6 Cadence contrast agent imaging

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510 (k) Number (if known):

Device Name: Intended Use:

CH6-2 Curved Array Transducer for use with SONOLINE Antares
Ultrasound imaging or fluid flow analysis of the human body as follows:

, ,						M	ode of Open	ation	<u> </u>	
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				]						
Fetal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8
Abdominal		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										11010 Z.J.J.4,U. 7.JO
Intraoperative Neurological										·
Pediatric		Ρ	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ										71010 210, 110,11,0
Neonatal Cephalic										
Adult Cephalic										<u> </u>
Cardiac										
Trans-esophageal										
Transrectal										· <u></u>
Transvaginal										<del></del>
Transurethral										<u> </u>
Intravascular									<del></del>	<del></del>
Peripheral vessel		P	P	P	1	Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic		$\neg \neg$				*-		<del></del>		11040 2,0,7,0,7,0
Musculo-skeletal Conventional										······································
Musculo-skeletal Superficial									·	<del></del>
Other (specify)		$\neg \uparrow$						<del></del> +		

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Note 2	Ensemble	tissue	harmonic	imaging
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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number K050034

510 (k) Number (if known):

Device Name: Intended Use:

PH4-1 Phased Array Transducer for use with SONOLINE Antares
Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic										<del></del>	
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8	
Abdominal		P	Р	Р		<u></u>	Р		BMDC	Note 2,3,4,5,7,8	
Intraoperative Abdominal										11000 2,0,1,0,1,0	
Intraoperative Neurological										<del></del>	
Pediatric		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8	
Small Organ					Ì			·	<del></del>	11010 21011101110	
Neonatal Cephalic										<del>.</del>	
Adult Cephalic					T i						
Cardiac						•				· · · · · · · · · · · · · · · · · · ·	
Trans-esophageal										· · · · · · · · · · · · · · · · · · ·	
Transrectal				1						· · · · · · · · · · · · · · · · · · ·	
Transvaginal										<del></del>	
Transurethral					7		<del></del>	``		<del></del>	
Intravascular										<del></del>	
Peripheral vessel		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8	
Laparoscopic										14010 2,0,4,0,7,0	
Musculo-skeletal Conventional							-				
Musculo-skeletal Superficial											
Other (specify)								···	<del></del>	<del></del>	

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

#### Additional Comments:

Note 2	Ensemble tissue harmonic imaging
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Note 3 SieClear multi view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \$\sqrt{0.50034}

510 (k) Number (if known):

Device Name: Intended Use: P10-4 Phased Array Transducer for use with SONOLINE Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

				,		M	ode of Oper	ation		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	1		T						<u></u>	<del></del>
Fetal										<del></del>
Abdominal		Ρ	Р	P	Р	Р	P		BMDC	Not- 00 4 5 5 0
Intraoperative Abdominal						<u> </u>			BIVIDE	Note 2,3,4,5,7,8
Intraoperative Neurological							-			
Pediatric		Р	Р	Р	Р	Р	P		BMDC	Note 2.2.4.5.7.0
Small Organ							· ·		DIVIDO	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	Р	Р	Р	P		BMDC	Note 2.2 4 5 7 2
Adult Cephalic						· · · · · ·	<del></del>	<del></del>	DIVIDO	Note 2,3,4,5,7,8
Cardiac		Р	Р	Р	Р	Р	P		BMDC	Note C O 4 E O E O
Trans-esophageal									DIVIDO	Note 2,3,4,5,6,7,8
Transrectal						<del></del>	<del></del>			
Transvaginal										<del></del>
Transurethral							<u> </u>			
Intravascular					-+		<del></del>		<del></del>	<del></del>
Peripheral vessel		Р	Р	P	Р	Р	P		BMDC	N=4-00 ( = = 0
Laparoscopic							<del></del>		DIVIDO	Note 2,3,4,5,7,8
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial								+		
Other (specify)								<del></del>		

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

## Additional Comments:

Note 2	Ensemble tissue harmonic imaging
Note 3	SieClear multi view spatial compounding
Note 4	Tissue Equalization Technology

Note 5
Note 6
Note 7
No

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number\_

C050034

510 (k) Number (if known):

Device Name: Indications For Use: VF13-5SP Linear Array Transducer for use with SONOLINE Antares

Diagnostic imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		[]				·			ì	
Fetal									1	·
Abdominal										······································
Intraoperative (Note 9)		Р	Р	Р	-	Р	P		ВМОС	Note 2,3,4,5,7,8
Intraoperative Neurological		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8
Pediatric		Р	Р	Ρ		Р	Р	<u> </u>	BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	Р	₽		Р	Р		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic										
Adult Cephalic								<del></del>		
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										····
Transurethral	]							_		······································
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional	]	Р	Р	Р		Р	Р	-	вмос	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Other (specify)							~~			<del></del>

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

#### Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate,	etc.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

C5F1 Curved array mechanical 3D transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<u>; — ; ; ; ; —</u>
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Abdominal		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										11010 2,0,4,0,1,0
Intraoperative Neurological				l		j		:		-
Pediatric		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ					· ·					11016 2,0,4,0,7,6
Neonatal Cephalic										
Adult Cephalic						***	<u> </u>			
Cardiac		- 1		i i	·		-			
Trans-esophageal										·
Transrectal										
Transvaginal										<del></del>
Transurethral			$\neg$		Ť				<del></del> +	
Intravascular							-		<del></del>	
Peripheral vessel		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										1100 2,3,4,3,7,8
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										<del>17</del>
Other (specify)			$\neg \neg$						—— <del>—</del>	

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

#### **Additional Comments:**

Note 2	Ensemble	tissue	harmonic	imaging
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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

3-Scape real-time 3D imaging Note 5

Note 7 B&W SieScape panoramic imaging Note 8

Power SieScape panoramic imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number\_

510 (k) Number (if known):

Device Name: Intended Use:

C7F2 Curved array mechanical 3D transducer for use with SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										· — <u>· — · · · · · · · · · · · · · · · ·</u>
Fetal		P	Р	P		Р	Р		ВМОС	Note 2,3,4,5,7,8
Abdominal		₽	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										2,01,101,10
Intraoperative Neurological						·				
Pediatric		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic						'				
Adult Cephalic										<del></del>
Cardiac						7				······································
Trans-esophageal								·		
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		вмрс	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

## Additional Comments:

Note 2 Ensemble tissue	harmonic	imaging
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Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal

and Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

EV9F4 Curved Array Transducer for use with SONOLINE Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic						<del></del>				
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal				•						<u></u>
Intraoperative Neurological										
Pediatric						·				
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		N	N	N ·		N	N		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										·
Transvaginal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Transurethral									-	
Intravascular					Ì				<del>-                                    </del>	
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										·
Musculo-skeletal Superficial										
Other (specify)										······································

N = new indication; P = previously cleared by FDA; E = added under Appendix E

#### Additional Comments:

Note 1	For example: breast	testes, thyroid, penis, prostate, e	to.
11016	I OI CAGITIDIO, DICASI.	. lestes, inviolu, benis, prostate, e	:FC:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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